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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/682,292

10/09/2003

Scott Wofford

41650.2

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7590

06/29/2006

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EXAMINER

ALTER, ALYSSA M

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/682,292	Applicant(s) WOFFORD ET AL.	
	Examiner Alyssa M. Alter	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2006.
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18-36, 38-52 and 54-70 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) ☒ Claim(s) 25-31, 33-36, 38-52, 54-66 and 68-70 is/are allowed.
 6) ☒ Claim(s) 1-11, 18-24 and 67 is/are rejected.
 7) ☒ Claim(s) 12-16 is/are objected to.
 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
 10) ☒ The drawing(s) filed on 09 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-16, 18-31, 33-36 and 38-70 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 21 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 20 recites the limitation "the cerebrovascular disease" in line 1. There is insufficient antecedent basis for this limitation in the claim, since cerebrovascular disease is not positively claimed, but merely inferentially included.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-11, 18-20, 22-24 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vu'Nguyen (US 5,425,752) in view of Fabian et al. (US 5,431,625) and in further view of Carroll et al. (US Patent Publication 20040073269 A1). Vu'Nguyen discloses a method of direct myostimulation using acupuncture needles of

approximately 3-6 cm (30-60 mm). Therefore, Vu'Nguyen discloses the claimed invention except for the current ramping and Hertz range.

Fabian et al. teaches that it is known to utilize ramping of current as set forth in column 1, lines 32-50, for the purpose of minimizing the shocking or stunning sensation a patient may receive during rapid changes in administered current level. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the delivering of stimulation as taught by Vu'Nguyen with a ramping of current as taught by Fabian et al., in order to minimize patient discomfort during the application of electrotherapy.

Carroll et al. teaches that it is known to utilize electric current at a frequency about 2500 Hz as set forth on page 2, paragraph 18, stimulation at a frequency of at least 1 kHz but no more than 20kHz for stimulation of the musculature. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electric current as taught by the modified Vu'Nguyen with the electric current as taught by Carroll et al., in order to modify treatment to meet specific patient needs. Furthermore, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (see MPEP 2144.05).

As to claims 2-3 and 23-24, the modified Vu'Nguyen discloses the claimed invention except for the current rate or pulse width. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the current rate and pulse width, since it is well known to modify current parameters and it has been

held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (see MPEP 2144.05).

As to claim 4, Since the treatment is applied for several sessions for about 3-6 weeks, there obviously are periods of stimulation and rest.

As to claims 5-8 and 18-19, the modified Vu'Nguyen discloses the claimed invention except for the periods of time for stimulation and rest. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the treatment times, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (see MPEP 2144.05).

As to claim 10, the specific muscles in need of rehabilitation are identified prior to the insertion of the acupuncture needles.

As to claim 20, the modified Vu'Nguyen discloses the claimed invention except for the inclusion of physical therapy during treatment. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the treatment to include physical therapy since it was known in the art that physical therapy helps strengthen weakened or atrophied muscles.

As to claim 67, the modified Vu'Nguyen discloses the claimed invention except for the Russian Stimulation Device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the electrical stimulation device as taught by Vu'Nguyen with a Russian Stimulation Device since both devices

provided the muscles with electrical stimulation and are thus, functional equivalents in the medical stimulation art.

Claim Objections

1. Claim 22 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Allowable Subject Matter


1. Claims 12-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

2. Claims 25-31, 33-36, 38-52, 54-66 and 68-70 are allowed. The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fails to teach or reasonably suggest a method of restoring the functionality of weakened and atrophied muscles by cerebrovascular disorder with 2 needles about 25-75 mm in length, inserted at a depth sufficient to extent into the proximal and distal motor points of a muscle and delivering electric current at 40-60 pulses per second with a pulsed width of 200-350 microseconds for a cycling of stimulation and rest for about 5-15 minutes with stimulation and rest periods lasting 5-50 seconds, in combination with the other elements in the claims.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alyssa M. Alter whose telephone number is (571) 272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



ROBERT E. PEZZUTO
SUPERVISORY PRIMARY EXAMINER



Alyssa M Alter
Examiner
Art Unit 3762
